



Atty. Docket No. A34720-PCT-USA-A
071986.0227

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re Application of : Johann Eibl

Serial No. : 09/998,575 Examiner : Jon P. Weber

Filed : November 16, 2001 Group Art Unit : 1651

For : MEDICAMENT FOR TOPICAL APPLICATION

**PETITION UNDER 37 C.F.R. §1.182 TO REQUEST
RECONSIDERATION OF SPECIES ELECTION REQUIREMENTS**

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

July 8, 2004

Date of Deposit

Lisa B. Kole
Attorney Name

Signature

35,225

PTO Registration No.

July 8, 2004

Date of Signature

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In the Official Action dated March 12, 2004, the Examiner maintained two species election requirements that Applicant traversed in its response dated December 29, 2003. For reasons set forth below, Applicant requests that the species election requirements be reconsidered on grounds that they do not allow Applicant the opportunity to prosecute his broadest claim.

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1. THE INVENTION

The present invention, in the broadest sense, is captured by claim 1:

1. A topical medicament intended for stopping bleeding, closing a wound, or promoting wound healing in a subject in need of such treatment, comprising the following active agents in therapeutic amounts:

- (i) an agent selected from the group consisting of fibrinogen and fibrin;
5 (ii) thrombin;
(iii) a transglutaminase; and
(iv) a serpin protease inhibitor which does not inhibit collagenase and elastase;

wherein the active agents may be obtained from a source selected from the group of allogenic plasma, allogenic tissue, and recombinant production; and wherein an active substance of allogenic origin is subjected to a process selected from the group consisting of virus depletion, virus inactivation and a combination thereof; provided that where such a process is applied to the serpin protease inhibitor, it is not applied in the presence of one or more of the other active agents.

Thus, the present invention relates to compositions comprising active agents (i)-(iv), and in addition has four further aspects. First, the source of the four listed active agents may be allogenic plasma or tissue or may be recombinantly produced. Second, an active agent is subjected to one or more process that depletes and/or inactivates virus. Third, the serpin is a member of this (serine protease inhibitor) superfamily that does not inhibit collagenase and elastase (so that "the inhibition of proteases released by the granulocytes immigrated into the wound area is largely avoided such that the setting in of wound healing will not be impeded" (in the specification at page 3 line 22 through page 4 line 2)). Fourth, as regards the serpin component, viral depletion/activation is carried out in the absence the other active agents, which has been found to improve its effectiveness.

2. THE RESTRICTION REQUIREMENT

130 claims were originally filed, directed to (i) topical medicaments (claims 1-104); (ii) a process for preparing a fibrinogen-containing solution (claims 105 and 106); (iii) a medicament comprising a highly purified fibrinogen (claims 107 and 108); (iv) a process for obtaining a pathogen-free active substance (claim 109); (v) a process for covalently binding an active agent to a biological matrix (claim 110); (vi) a process for preparing a fibrin-containing gel (claim 111-116); (vii) a process for solidifying a fibrin-containing gel (claims 117 and 118); (viii) a lyophilized fibrin-containing gel (claims 119 and 120); (ix) a process for preparing a highly viscous fibrinogen-containing solution (claim 121); (x) a process for determining the adherence of a fibrin clot in a wound bed (claim 122); (xi) a method of treating a wound of a subject (claims 123-130). The Examiner identified twelve separate inventions, one of which is embodied in claims 1-104, which were elected for further prosecution without traverse.

3. THE SPECIES ELECTION REQUIREMENTS

In addition to the restriction requirement, the Examiner issued two species election requirements.

In the first species election requirement, the Examiner required Applicant to select one of the following species: a structural protein (claims 2-5), a cell stimulating factor (claims 5-8), an enzyme or enzyme inhibitor (claims 9-16), an antiadherent, antioxidant or antimicrobial (claims 17-32), a blood coagulation zymogen (claims 33-64) or a particulate cell element (claims 65-95). None of these species is recited in claim 1. Applicant traversed the requirement, but to be responsive elected the species of structural protein.

In the second species election requirement, the Examiner required Applicant to select a species among the species of structural proteins selected. Applicant traversed the requirement, but to be responsive elected the species, allogenic collagen.

4. THE SPECIES ELECTION REQUIREMENTS ARE IMPROPER

In the Official Action dated March 12, 2004, the Examiner rejects Applicant's traversal of the species election requirement, contending:

[t]he additional components are active ingredients that would materially affect the basic and novel characteristics of the claimed invention. Accordingly, it is proper to consider that searching each and every one of the added active ingredients could entail burden. Burden is established because each of the possible ingredients requires a separate search inasmuch as the different active ingredients are not classified together or recognized in the art as being coextensive.

The Examiner goes on to state:

Claims 3-98 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim (*vide infra*).

Applicant points out that structural proteins (the subject of the first species election requirement), such as allogenic collagen (the subject of the second species election requirement), arise in the claims as a further element – a fifth element – added (by dependent claims) to the composition of claim 1. For example, claim 2 recites:

2. The medicament of claim 1, further comprising allogenic collagens subjected to a process selected from the group consisting of virus depletion, virus inactivation, and a combination thereof.

By imposing the species election requirement, the Examiner is *presupposing* that claim 1 is not allowable without providing an examination on the merits. The Examiner's contention, that consideration of the dependent claims creates an unreasonable burden to do

extensive searching, is not on point. If an independent claim is allowable, there is no need to search the additional subject matter of dependent claims, as dependent claims need not add a separately patentable feature.

**5. REQUEST THAT THE SPECIES REQUIREMENTS
BE LIFTED AND THAT CLAIMS 3-98 BE CONSIDERED**

Applicant should be given the opportunity to defend the patentability of claim 1 without additional limitations imposed. In the pending official action, claim 1 is rejected, and the Examiner could have properly rejected all its ultimately dependent claims (2-104) as dependent on a rejected claim. To instead withdraw claims 3-98 from consideration is inappropriate. Applicant would further note that if, for the sake or argument only, Applicant added a further element to claim 1 in response to the pending rejection, Applicant would then have the further burden to explain why the addition of that element would obviate the rejection, relieving the burden placed on the Examiner. If the Examiner believed that the addition of a further element produced too great a burden, he has procedural recourse.

5. CONCLUSION

For all the foregoing reasons, it is respectfully requested that the species election requirements be withdrawn and that all the claims of the elected group, claims 1-104, be considered. A check in the amount of \$130.00 is enclosed to cover your fee; please charge any additional fees associated with this Petition to Deposit Account No. 02-4377. A copy of this page is attached.

Respectfully submitted,



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ATTORNEYS FOR APPLICANTS